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| EXAMINER | | | | |
| YEAGER, RAYMOND P | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,451

Applicant(s)

JOKINEN ET AL.

Examiner

RAYMOND P. YEAGER

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 22-26, 28, 30-32, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 27, 29 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 08/24/2006; 10/26/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 to 37 are pending.

Election/Restriction

The examiner apologizes for the typographical error resulting in the placement of claim 36 in both groups II and III(a) and claim 37 in both groups II and III(a). Claims 36 and 37 are drawn to a *process of using an SiO₂ monolith* in group III(a) and III(b) while claims 20 to 35 are drawn to a *bioresorbable SiO₂ monolith, coating, or particle*. The examiner thanks the applicant for electing the product in group 2 which is drawn to claims 20 to 35. Further, the applicant is forewarned that should claims 36 or 37 undergo examination at a later date, that they are use claims drawn to a nonstatutory class thus these claims would need to be properly amended to be examined. The examiner apologies for any confusion this has caused.

Applicant's election with traverse of group II, claims 20 to 35 in the reply filed on 05/26/2009 is acknowledged. The traversal is on the ground(s) that a motivation to combine was not provided and the instantly claimed product exhibits a fast bioresorption rate. This is not found persuasive because a rationale was provided on page 9, lines 9-22) and the fast bioresorption rate is discussed in the Claim Rejections - 35 USC § 103 section below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 to 19 and 36 to 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/26/2009.

Applicant's election of the species noted below in the reply filed on 05/26/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

The applicant elects the following species:

- The embodiment of the sol-gel: **sol-gel derived SiO₂ monolith**;
- The restriction communication of 2/26/2009 also indicated an election of species requirement which is only partially applicable to the currently elected product of Group II. Applicant's election of a sol-gel derived SiO₂ monolith containing a biologically active agent is acknowledged. All other requirements for election of species set forth in the communication of 2/26/2009 are not applicable to the product claims of Group II as currently claimed.

Claims 22 to 26, 28, 30 to 32, and 36 to 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/26/2009.

Priority

Application 10/590,451 (08/24/2006) is a national stage entry of PCT/FI05/50046 (02/22/2005) per 35 USC 371 and claims benefit of 60/548,113 (02/27/2004), claims foreign priority to Finland 20040312 (02/27/2004) per 35 USC 119. The '113 application and the '312 foreign document provide support for claims 21, 27, 29, and 33 to 35. Thus claims 21, 27, 29, and 33 to 35 are considered to have an effective priority date of 02/27/2004.

Information Disclosure Statement

The Information Disclosure Statements (2) have been reviewed. Applicants are reminded of their duty to disclose all information known to them to be material to patentability as defined in 37 CFR 1.56.

Objection - Specification (Abstract)

The abstract of the disclosure is objected to because the most recent abstract submitted on 08/24/2006, exceeds the maximum word requirement. Correction is required. See MPEP § 608.01(b).

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Objection – Claims

Claims 21, 27, 29, and 33 to 35 are objected to because of the following informalities: These claims are dependent on a non-elected claim (i.e. a claim in a non-elected group). Appropriate correction is required.

Claims 21, 27, 29, and 33 to 35 are objected to because of the following informalities: The applicant has been inconsistent when amending the claims. The applicant has used both the strikethrough (i.e. ~~strikethrough~~) and double brackets (i.e. [[double brackets]]) to indicate deleted portions of the claims. The claims must be amended in compliance with 37 CFR § 1.121, which notes: "The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 27, 29, and 33 to 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortesuso, 2001 (provided in the 02/26/2009 restriction requirement) (Kortesuso Dissertation, University of Helsinki, 2001) as evidenced by Kortesuso et al, 2001a (*Journal of Controlled Release*, vol. 76:227-238).

Applicant claims a bioresorbable sol-gel derived SiO₂ monolith comprising a biologically active agent with a dissolution rate greater than 0.35 (instant claim 21) or 0.5 (instant claim 27) weight percent per hour (instant claim 27) in TRIS buffer at pH = 7.4 and 37° C and also claims a dissolution rate of 0.001 to 0.06 weight percent per hour (instant claim 29). Further the biologically active agent is claimed to be a peptide, protein, or cell wherein the dissolution rate of the SiO₂ monolith is claimed to be greater than 0.04 (instant claim 33) or 0.5 (instant claim 34) weight percent per hour in TRIS buffer at pH = 7.4 and 37° C and also claims a dissolution rate of 0.001 to 0.15 weight percent per hour (instant claim 35).

Determination of the scope and content of the prior art - (MPEP 2141.01)

Kortesuso, 2001 teaches a biodegradable (page 25, section 5.1.2) sol-gel derived SiO₂ monolith (page 10, section 2.3, paragraph 1 and page 25, section 5.1.2) which may incorporate cells (page 11, paragraph 1). Kortesuso, 2001 teaches the degradation over a 30-hour dissolution period was 16.9 to 25 percent (page 25, section 5.1.1, paragraph 2) which would be a dissolution rate of 0.563 to 0.833 weight percent per hour (limitations in instant claims 21, 27, 33, and 34). Degradation studies were performed at pH 7.4 and at 37° C in simulated body fluid (SBF) (page 22, section 4.4, paragraph 1). As evidenced by Kortesuso et al, 2001a, SBF contains TRIS buffer (page 228, column 2, section 2.3, paragraph 1). Further, Kortesuso, 2001 teaches the pH and the water to alkoxide (or inorganic silicate) ratio affects the degradation rate (page 28, table 2) as does the surface area and geometry of the sol-gel derived SiO₂ (page 7, paragraph 3). Kortesuso, 2001 also teaches the porous structure alters the degradation rate of the sol-gel derived SiO₂ monolith (page 31, section 6.1) and larger gel monoliths degrade faster than smaller ones (page 35, section 6.1.3, paragraph 2). Kortesuso, 2001 also teaches the degradation rate of the silica xerogel can be modified by varying the composition of starting materials and subsequently the structure of the silica gel matrix

by varying the manufacturing method from casting to spray drying (page 35, section 6.1.3, paragraph 2). Kortesuso, 2001 also indicates that the dissolution of a monolith *in vivo* may be about 10-fold slower than *in vitro* (page 35, section 6.1.3, paragraph 3), which results in dissolution rates of 0.056 to 0.083 weight percent per hour based on the rates discussed *supra* (limitations in claims 29 and 35) and as evidenced by Kortesuso et al, 2001a *supra*, these monoliths are administered with TRIS. Kortesuso et al, 2001 does not explicitly exemplify the instantly claimed monoliths.

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a sol-gel derived SiO₂ monolith as taught by Kortesuso, 2001, with optimized surface area, geometry, pH and water/alkoxide ratio and with a higher (~0.5 weight percent per hour) or lower (~ 0.05 weight percent per hour) degradation rate as taught by Kortesuso, 2001. It further would have been obvious to one of ordinary skill in the art to use the sol-gel derived monoliths to deliver any biological agent of interest especially heat sensitive agents as taught by Kortesuso 2001 (abstract, page iii) including cells, peptides and proteins.

One of ordinary skill in the art would have been motivated to do this because Kortesuso, 2001 teaches the sol-gel derived SiO₂ monoliths are a means to control the release rate of therapeutic substances (page 31, section 6.1, paragraph 1).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 27, 33, and 34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 25, and 30 to 33 of copending Application No. 09/913,643 in view of Kortessuo et al, 2001a. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are overlapping in scope.

The instant application claims a SiO₂ monolith comprising cells with a dissolution rate from greater than 0.04. The '643 application claims a silica sol fiber with a solubility rate of 0.2 to 20 weight percent per hour in simulated body fluid which as evidenced by Kortessuo et al, 2001a *supra* SBF contains TRIS and the dissolution test is performed at

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pH 7.4 and at 37° C. This solubility in SBF is considered the bioresorption rate and as such make obvious instant claims 21, 27, 33, and 34.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are all; all claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

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